

§ 862.1175

treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

(b) *Classification.* Class II.

§ 862.1175 Cholesterol (total) test system.

(a) *Identification.* A cholesterol (total) test system is a device intended to measure cholesterol in plasma and serum. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

(b) *Classification.* Class I.

§ 862.1177 Cholyglycine test system.

(a) *Identification.* A cholyglycine test system is a device intended to measure the bile acid cholyglycine in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.

(b) *Classification.* Class II.

§ 862.1180 Chymotrypsin test system.

(a) *Identification.* A chymotrypsin test system is a device intended to measure the activity of the enzyme chymotrypsin in blood and other body fluids and in feces. Chymotrypsin measurements are used in the diagnosis and treatment of pancreatic exocrine insufficiency.

(b) *Classification.* Class I.

§ 862.1185 Compound S (11-deoxycortisol) test system.

(a) *Identification.* A compound S (11-deoxycortisol) test system is a device intended to measure the level of compound S (11-deoxycortisol) in plasma. Compound S is a steroid intermediate in the biosynthesis of the adrenal hormone cortisol. Measurements of compound S are used in the diagnosis and treatment of certain adrenal and pituitary gland disorders resulting in clinical symptoms of masculinization and hypertension.

(b) *Classification.* Class I.

§ 862.1187 Conjugated sulfolithocholic acid (SLCG) test system.

(a) *Identification.* A conjugated sulfolithocholic acid (SLCG) test system is a device intended to measure

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the bile acid SLCG in serum. Measurements obtained by this device are used in the diagnosis and treatment of liver disorders, such as cirrhosis or obstructive liver disease.

(b) *Classification.* Class II.

§ 862.1190 Copper test system.

(a) *Identification.* A copper test system is a device intended to measure copper levels in plasma, serum, and urine. Measurements of copper are used in the diagnosis and treatment of anemia, infections, inflammations, and Wilson's disease (a hereditary disease primarily of the liver and nervous system). Test results are also used in monitoring patients with Hodgkin's disease (a disease primarily of the lymph system).

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.1195 Corticoids test system.

(a) *Identification.* A corticoids test system is a device intended to measure the levels of corticoids (hormones of the adrenal cortex) in serum and plasma. Measurements of corticoids are used in the diagnosis and treatment of disorders of the cortex of the adrenal glands, especially those associated with hypertension and electrolyte disturbances.

(b) *Classification.* Class I.

§ 862.1200 Corticosterone test system.

(a) *Identification.* A corticosterone test system is a device intended to measure corticosterone (a steroid secreted by the adrenal gland) levels in plasma. Measurements of corticosterone are used in the diagnosis and treatment of adrenal disorders such as adrenal cortex disorders and blocks in cortisol synthesis.

(b) *Classification.* Class I.

§ 862.1205 Cortisol (hydrocortisone and hydroxycorticosterone) test system.

(a) *Identification.* A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device intended to